K131346

Vol 4
File 001

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510(k) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

1. **Submitter's Identification:**

Microlife Intellectual Property GmbH, Switzerland
Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: Jan 16, 2013

Contact: Mr. Gerhard Frick
Vice President of Technical and Service
Microlife Intellectual Property GmbH, Switzerland
Tel: +41 79 216 0070
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2. **Name of the Device:**

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GT1-6X

Regulation Number: 21 CFR Part 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: II
Product Code: DXN

3. **Information for the 510(k) Cleared Device (Predicate Device):**

1. Microlife Automatic Talking Blood Pressure Monitor, Model BP3AP1-3E, K111652, Microlife Intellectual Property GmbH

2. Microlife Upper Arm Automatic Digital Blood Pressure Monitor BP3MC1-PC, K061471, Microlife Intellectual Property GmbH

4. **Device Description:**

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GT1-6X is designed to measure systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive MAM (Microlife Average Mode) technique in which an inflatable cuff is wrapped around the upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses a capacitor pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the "oscillometric method".

And the device has Irregular Heartbeat Detection (IHD) function. It detects the appearance of irregular heartbeat during measurement and the irregular heart beat symbol " " is displayed on the LCD screen if any irregular heart beat signal has been detected. In addition, the device has a traffic light function. And the device can be used in connection with your personal computer (PC) running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

The device features an interactive touch screen which operates similarly to traditional buttons, but requires only a light touch of the finger to operate.

5. **Intended Use:**

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GT1-6X is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm.

The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected.

The device can be used in connection with your personal computer (PC) running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

6. **Comparison to the 510(k) Cleared Devices (Predicate Devices):**

The subject BP3GT1-6X and the predicate device model BP3AP1-3E, use the same oscillometric method with the same fundamental scientific technology to determine the systolic and diastolic blood pressure and pulse rate. Upper arm cuff is inflated automatically by pump and the pressures are transferred via tubing to a sensor in these two units.

They differ by the talking function, MAM, back light, PC-link function and the way to operate the device. The talking function is removed from the subject device; while the MAM, backlight, PC-link function is added to the subject device. The way to operate the predicate device is to press the button, and the subject device requires a light touch of the finger on the screen. But those differences do not affect the accuracy and normal use of this device because they use the same fundamental scientific technology based on clinical declaration of identity and the Declaration of Clinical Identity.

The subject BP3GT1-6X uses the same oscillometric method as the predicate BP3MC1-PC to determine the systolic and diastolic blood pressure and pulse rate. The have the same MAM, backlight, traffic light, PC-link, IHD function and intended use. Based upon the aforementioned information, the two devices are substantially equivalent.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GT1-6X in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance requirements.

The following testing was conducted:

a. Reliability Test - Storage test
b. Reliability Test - Operating test
c. Reliability Test - Vibration test
d. Reliability Test - Drop test
e. Reliability Test - Life test
f. EMC Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GT1-6X tested met all relevant requirements of the aforementioned tests.

8. **Discussion of Clinical Tests Performed:**

The subject device Model BP3GT1-6X is from the technical point of view, identical to the predicate blood pressure monitor Model BP3AP1-3E. The differences between them do not relate to blood pressure measurement technology, so the clinical accuracy in terms of blood pressure detection will not be affected. Therefore repeated clinical test in accordance with the standard ANSI/AAMI SP10 is not necessary.

9. **Software Information:**

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". In addition, since our device requires the use of off-the-shelf software to operate the PC-link function, we adhered to the FDA September 1999 document "Guidance for Off-The-Shelf Software Use in Medical Devices".

10. **Conclusions:**

We have demonstrated that there are no significant differences between the Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GT1-6X and the predicate devices, Model BP3AP1-3E and Model BP3MC1-PC in terms of safety and effectiveness based on electrical, mechanical and environmental test results per the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and the ANSI/AAMI Voluntary Standard, SP10: 2008.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

June 6, 2013

Microlife Intellectual Property Gmbh
C/O Susan Goldstein-Falk
55 Northern Blvd., Suite 200
Great Neck, NY 11021 US

Re: K131346
Trade/Device Name: Microlife upper arm automatic digital blood pressure monitor (Model BP3GT1-6X)
Regulation Number: 21 CFR 870.1130
Regulation Name: Auto-Inflation Oscillometric Digital Blood Pressure Monitor
Regulatory Class: Class II
Product Code: DXN
Dated: May 8, 2013
Received: May 9, 2013

Dear Susan Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K131346

Indications for Use

510(k) Number (if known): _____

Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GT1-6X

Indications For Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GT1-6X is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm.

The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected.

The device can be used in connection with your personal computer (PC) running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

Prescription Use _____ **AND/OR** **Over-The-Counter Use** __X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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